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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,629	11/13/2003	Kotikanyadanam Sreekrishna	9423	5723

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THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
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EXAMINER	
DUNSTON, JENNIFER ANN	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,629	SREEKRISHNA ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *3-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Appendix I*.

DETAILED ACTION

Claims 1-8 are pending in the instant application.

Any rejection of record in the previous office actions not addressed herein is withdrawn. New grounds of rejection are presented herein that were not necessitated by applicant's amendment of the claims since the office action mailed 1/27/2006. Therefore, this action is not final.

Election/Restrictions

Applicant's election without traverse of Group I and SEQ ID NO: 2 (*Homo sapiens* Ubiquitous Receptor) in the reply filed on 11/16/2004 is acknowledged.

Claims 3-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/16/2004.

Claims 1 and 2 are under consideration as they read on SEQ ID NO: 2.

Specification

The amendment filed 10/20/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: (i) SEQ ID NOs: 17 and 18; and (ii) the amendment of the paragraph bridging pages 27-28 to recite, "nucleotide position 2915 change

from T to C causing a codon change from CCT to CCC) from the published sequence (SEQ ID NO: 18)."

The specification has been amended to define "truncated hairless protein (HRt)" as the sequence provided as SEQ ID NO: 17 (page 5, line 34 to page 6, line 10). Further, the specification has been amended to indicate that SEQ ID NO: 18 is the nucleic acid sequence encoding amino acids 490 to 1182 of mouse hairless protein (page 7, lines 7-35). The sequence listing has been amended to include new sequences, SEQ ID NOS: 17 and 18, which were not present in the original sequence listing.

The specification indicates that the truncated hairless protein is amino acid residues 490-1182 of the C-terminal portion of mouse hairless (HR) protein (e.g. page 5, line 34 to page 6, line 10). This sequence should be contained in SEQ ID NO: 17. However, a search of the commercial sequence databases using SEQ ID NO: 17 did not identify a single sequence of 100% identity to SEQ ID NO: 17. For example, SEQ ID NO: 17 is 99.4% identical to amino acids 490-1182 of I48378, which is 100% identical to GenBank Accession No. CAA83587 (see the attached sequence alignments in Appendix I for SEQ ID NO: 17 and I48378). There are three mismatches between the protein of instant SEQ ID NO: 17 and the protein of I48378. For clarity, a second alignment comparing the protein encoded by Z32675 and the protein of I48378 is provided (mailed 1/27/2006). This alignment demonstrates that the proteins of I48378 and the protein encoded by Z32675 are 100% identical. An inspection of the sequences provided by Applicant and the sequences known in the art as mouse hairless protein indicates that the sequence provided by Applicant is not amino acid residues 490-1182 of mouse hairless protein.

The specification provides support for the amino acid sequence of mouse hairless protein encoded by GenBank Accession No. Z32675 (e.g. page 7, lines 7-35). However, the sequence provided in the sequence listing is not identical to this sequence. Thus, the amendment is a departure from the specification as originally filed.

The paragraph bridging pages 27-28 describes the location of mutations in mouse HR cDNA obtained by PCR amplification and cloning. The as-filed specification provided nucleotide positions with numbering relative to the fragment amplified, and the amendment filed 10/20/2009 re-numbered the positions relative to the full-length cDNA. For example, position 321 was replaced with position 2165, and position 756 was replaced with position 2600. There's a 1844 nucleotide difference between each of the two numbers. However, position 1076 was replaced with 2915, which is not a 1844 nucleotide difference.

Position 1076 in SEQ ID NO: 18 is not a T. Thus, one would have recognized that the originally filed paragraph contains an error. While there is no in *haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). In the instant case, one would have recognized that the reference to position 1076 (or position 1076+1844 = position 2920) was in error, because there is no T at position 1076 to be changed to C. However, one would not have recognized the appropriate correction. For example, another correction could have been position 1077 (or position 1077 + 1844 =

position 2921), to identify a T, where a T to C mutation causes a codon change from CCT to CCC.

Response to Arguments - Specification

Applicant's arguments filed 4/27/2006 and 10/20/2009 have been fully considered but they are not persuasive. The responses essentially assert that the specification has been amended to correct typographical errors in the sequence listing. This argument is not found persuasive, because the typographical errors are still present. For these reasons, and the reasons made of record in the previous office actions, the objection is maintained.

Claim Rejections - 35 USC §§ 101, 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

When determining whether the utility of an invention has been described, one determines whether applicant has described a well-established utility. If not, it is determined whether applicant has made an assertion of specific, substantial and credible utility. A credible utility is

assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for use. In contrast to general utility, a specific utility will be specific to the claimed subject matter. A substantial utility defines a real world utility of the invention, and utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world' context use are not substantial utility (see utility guidelines, Federal Register January 5, 2001, Vol. 66, No. 5, pages 1092-1099).

Claim 1 is drawn to a composition comprising a complex comprising a mouse HRt protein and a human Ubiquitous Receptor (UR). Claim 2 limits the human UR to the sequence encoded by SEQ ID NO: 2.

The specification of the instant application discloses that the present invention provides compositions of hairless protein-hairless protein interacting partner complexes (HR-IP) determined by the present inventors using yeast two- hybrid technology. The hairless protein interacting partners provided by the present invention are listed in Table 1 and include the human Ubiquitous Receptor (UR) (e.g., page 3, line 17 to page 4, line 16; page 6, lines 11-26; Example 1; Table 1).

However, the instant specification does not teach any functional characteristics of the composition comprising a complex comprising a mouse HRt protein and the Ubiquitous Receptor (UR) as the human interacting partner protein. The specification does not disclose the complex in the context of a cell or organism or any methods or working examples that indicate the complex of the instant invention is involved in any activities or diseases states related to hair growth or hair loss. Since significant further research would be required of the skilled artisan to determine how the complex comprising the **mouse** HRt protein and the **human** UR as the

interacting partner protein is involved any activity, the asserted utilities are not substantial. In addition, it is not clear how a complex comprising a mouse protein with a human interacting partner can have specific utility for the activities of hair growth or beautification and/or improvement benefits in humans, since the interaction of a mouse protein and human protein will not occur in nature in the human. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed the composition comprising a complex comprising a mouse HRt protein and the UR as the human interacting partner protein:

1) to assay a test compound for agonist or antagonist activity for a composition comprising the complex (e.g., page 3, lines 18-19; page 4, lines 17-25, page 13, line 13 to page 18, line 15; page 31, line 3 to page 33, line 4), where the agonists or antagonists are used to inhibit or increase hair growth on a surface in a subject comprising applying to the surface a growth inhibiting or growth increasing compound having agonist or antagonist activity for a composition for a time sufficient to increase or decrease the amount of hair on the surface (e.g., page 4, lines 26-34; page 8, lines 13-18); and

2) to prepare polyclonal and monoclonal antibodies, antibody fragments, humanized antibodies, single chain antibodies for affinity purification, detection and/or other functional studies, where the antibodies specifically bind the complex (e.g., page 9, lines 19-25).

Each of these shall be addressed in turn.

1) To assay a test compound for agonist or antagonist activity for a composition comprising the complex. This asserted utility is not specific or substantial. Such assays can be performed with a composition comprising any proteins or with any protein complexes besides a

mouse HRt protein. Nothing is disclosed about how the claimed composition comprising the claimed complex is affected by the compounds. Additionally, the specification discloses nothing specific or substantial for the composition comprising a complex comprising a mouse HRt protein and the human UR that can be identified/selected/validated by this method. Since this asserted utility has not been established for the composition comprising complex comprising a mouse HRt protein and the ubiquitous receptor UR as the human interacting partner protein, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Further, the specification does not disclose the tissues or cell types in which the claimed composition comprising the complex comprising a **mouse** HRt protein and the **human** UR is expressed. The specification also discloses nothing about the normal levels of expression and activities of the claimed the complex comprising the mouse HRt protein and the human UR polypeptide in hair follicles or on the skin. The specification does not disclose any disorders associated with hair loss or hair growth associated with the claimed composition comprising the claimed complex. Furthermore it is not known if promoting the interaction of the complex would be desirable for hair growth, or if it is the inhibition of this interaction which would be desired. Significant further experimentation would be required of the skilled artisan to identify subject and surface affected by hair loss or hair growth. Since this asserted utility has not been established for the claimed the composition comprising complex comprising a mouse HRt protein and the human UR, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) To make antibodies, or fragments thereof for affinity purification, detection and/or other functional studies. The antibodies will bind to the complex of the mouse HRt protein and

the human UR. However, this asserted utility is not specific or substantial. Antibodies can be made to any protein or protein complex. Antibodies to a complex do not have a specific and substantial use if the complex does not have a specific and substantial use. Using the antibodies for further functional studies does not provide a specific and substantial use. Such assays can be performed with any composition. Performing functional studies so that the complex could be used in a real world sense does not provide a substantial utility.

Therefore, the claimed invention does not have specific, substantial utility.

Claims 1 and 2 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

The claims are drawn to a composition comprising a mouse HRt protein. The specification states, "By 'truncated hairless protein (HRt)' is meant the sequence provided as SEQ ID NO: 17" (page 5, line 34 to page 6, line 1). However, this is not a limiting definition, because the specification goes not to state that "Derivatives, fragments, or analogs of HR known to one of skill in the art in light of the present disclosure are considered equivalents of HR."

(page 6, lines 2-3). At the paragraph bridging pages 27-28, the specification describes the sequence of the HRt protein used in the yeast two-hybrid assay, where the HRt protein is encoded by a nucleic acid sequence obtained from PCR amplification of a cDNA molecule, and where the amplified and cloned nucleic acid sequence contains mutations relative to the prior art sequence of SEQ ID NO: 18. The claims encompass this disclosed variant.

In the amendment filed 10/20/2009, the paragraph bridging pages 27-28 was amended to recite, "nucleotide position 2915 change from T to C causing a codon change from CCT to CCC) from the published sequence (SEQ ID NO: 18)." The reply filed 10/20/2009 asserts that the amendment is supported by counting the nucleotides in the HR gene sequence on page 7719 of the Begona reference, the relevant parts of which were incorporated by reference at page 33, lines 28-29.

The paragraph bridging pages 27-28 describes the location of mutations in mouse HR cDNA obtained by PCR amplification and cloning. The as-filed specification provided nucleotide positions with numbering relative to the fragment amplified, and the amendment filed 10/20/2009 re-numbered the positions relative to the full-length cDNA. For example, position 321 was replaced with position 2165, and position 756 was replaced with position 2600. There's an 1844 nucleotide difference between each of the two numbers. However, position 1076 was replaced with 2915, which is not an 1844 nucleotide difference.

Position 1076 in SEQ ID NO: 18 is not a T. Thus, one would have recognized that the originally filed paragraph contains an error. While there is no in *haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An amendment to correct an obvious error does not constitute new matter

where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). In the instant case, one would have recognized that the reference to position 1076 (or position 1076+1844 = position 2920) was in error, because there is no T at position 1076 to be changed to C. However, one would not have recognized the appropriate correction. For example, another correction could have been position 1077 (or position 1077 + 1844 = position 2921), to identify a T, where a T to C mutation causes a codon change from CCT to CCC.

Furthermore, the specification indicates that the truncated hairless protein is amino acid residues 490-1182 of the C-terminal portion of mouse hairless (HR) protein (e.g. page 5, line 34 to page 6, line 10). This sequence should be contained in SEQ ID NO: 17. However, a search of the commercial sequence databases using SEQ ID NO: 17 did not identify a single sequence of 100% identity to SEQ ID NO: 17. For example, SEQ ID NO: 18 is 99.4% identical to amino acids 490-1182 of I48378, which is 100% identical to GenBank Accession No. CAA83587 (see the attached sequence alignments in Appendix I for SEQ ID NO: 17 and I48378). There are three mismatches between the protein of instant SEQ ID NO: 17 and the protein of I48378. For clarity, a second alignment comparing the protein encoded by Z32675 and the protein of I48378 is provided (mailed 1/27/2006). This alignment demonstrates that the proteins of I48378 and the protein encoded by Z32675 are 100% identical. An inspection of the sequences provided by Applicant and the sequences known in the art as mouse hairless protein indicates that the sequence provided by Applicant is not amino acid residues 490-1182 of mouse hairless protein.

The specification provides support for the amino acid sequence of mouse hairless protein encoded by GenBank Accession No. Z32675 (e.g. page 7, lines 7-35). However, the sequence provided in the sequence listing is not identical to this sequence. Thus, the amendment is a departure from the specification as originally filed.

The original specification, drawings and claims were thoroughly reviewed and no support could be found for the amendment. Accordingly, the amendment is a departure from the specification and claims as originally filed, and the passages that Applicant has provided do not provide support.

Response to Arguments - 35 USC § 112

The rejection of claims 1 and 2 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment to the sequence listing and specification.

With respect to the rejection of claims 1 and 2 under 35 U.S.C. 112, first paragraph (new matter), Applicant's arguments filed 4/27/2006 and 10/20/2009 have been fully considered but they are not persuasive.

The responses essentially assert that the typographical errors in the sequence listing and specification have been corrected. In the response filed 4/27/2006 it was asserted that the three mismatches between the protein of the sequence listing and the prior art are minor typographical errors in the sequence listing, which have been corrected. In the reply filed 10/20/2009, the response asserts that the correct nucleotide sequence finds support in the Begona reference (GenBank Z32675), the relevant parts of which were incorporated by reference.

These arguments are not found persuasive. The sequence listing filed 10/20/2009 still contains the mismatches relative to the prior art sequence.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Sreekrishna et al (US Patent Application Publication No. 2004/0086945 A1; see the entire reference).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Sreekrishna et al teach a composition comprising a complex of mouse HRt protein and human Ubiquitous Receptor (e.g., paragraph [0008]).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Dunston/
Examiner
Art Unit 1636